

Congress of the United States
Washington, DC 20515

November 5, 2020

Donald J. Trump
The White House
1600 Pennsylvania Ave., NW
Washington, DC 20500

Dear Mr. Trump,

As the COVID-19 pandemic continues to spread seemingly unabated throughout our country, we write today regarding your administration's elimination of the separate vaccine office, the National Vaccine Program Office (NVPO), within the Centers for Disease Control and Prevention (CDC). Your decision to merge the vaccine office with the infectious disease office was short-sighted in March 2019 and the failure to reverse course is equally short-sighted in light of the large vaccine initiative currently underway for COVID-19. Tracking the safety of a potential COVID-19 vaccine once one is in use is absolutely essential to providing a safe vaccine to millions of Americans. Missed opportunities in establishing a comprehensive testing strategy, securing the medical supply chain, and the lack of clear guidance on the virus have led to the United States seeing one of the worst outbreaks worldwide. We must take swift action today to ensure we do not make mistakes on our vaccine strategy. To that end we seek information about the ability of the infectious disease office to ensure the proper oversight of a potential COVID-19 vaccine.

Created by Congress in 1986, the NVPO was an independent coordinating office within the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health. NVPO became the key coordinator for existing components of the U.S. vaccine and immunization system under the National Vaccine Program. However, in March 2019, your administration effectively eliminated the NVPO when it merged the Office of HIV/AIDS and Infectious Disease Policy and the NVPO to become the Office of Infectious Diseases and HIV/AIDS Policy (OIDP). Within the new OIDP, there appears to be no designated leader responsible for vaccine safety. Without ownership over the vaccine safety elements of the Infectious Disease Office's work, we question the ability of your political staff to properly conduct oversight of any potential vaccine.

The pattern of eliminating entire offices and career scientists, such as the U.S. Agency for International Development's Emerging Pandemic Threats Program, or Dr. Rick Bright, who formerly led the efforts at the U.S. Biomedical Advanced Research and Development Authority (BARDA) to fund vaccines and therapeutics, is all too familiar to this administration. Career scientists within the government have decades of experience studying and tracking the long-term safety of vaccines. Sidelining our national experts, regarded as the best in the world, is tantamount to pandemic response malpractice. There are multiple vaccine candidates already engaged in large-scale human clinical trials and under previous administrations, an independent, coordinating body would be tracking safety and adverse events in those trials. In 2009, when the U.S. administered

the H1N1 vaccine to more than 80 million Americans, NVPO coordinated the creation of a monitoring plan and system built on a foundation that did not require patient reporting.

However, due to your decision to eliminate the independent vaccine office, there is currently no leader responsible for the vaccine safety effort and agency staff are reliant on relationships previously built across sub-agencies for unrelated projects to discuss vaccine safety. There are reports Americans are increasingly skeptical of the safety of a COVID-19 vaccine. This increased skepticism is the direct result of political interference by this Administration. American confidence in the safety and efficacy of any and all potential COVID-19 vaccines is of paramount importance to defeating this virus. In the interest of arresting the erosion of public confidence engendered by your administration, we request more information about vaccine safety oversight in light of the elimination of the NVPO as an independent concern:

1. What factors were considered by HHS in the decision to dismantle NVPO in March 2019? Please provide any documentation, including the study by career staff, that led to this decision.
2. Does HHS plan on naming an official to a leadership role who will be responsible for vaccine safety?
3. What offices is the infectious disease office coordinating with to leverage expertise across the FDA and CDC to track vaccine safety?
4. Why is HHS not utilizing the Post-Licensure Rapid Immunization Safety Monitoring (PRISM) system for vaccine safety tracking?
5. What steps is your administration taking to provide resources and expertise to the infectious disease office to monitor vaccine safety?
6. NVPO previously provided the framework for vaccination programs such as the National Adult Immunization Plan, which included strategies for equitable vaccine allocation, taking health disparities into account. Is HHS taking steps to build out a framework that focuses on equitable vaccine allocation? If so, who is leading this effort?
7. What steps is HHS taking to build public confidence in your government's vaccine work? Specifically, how has your administration performed outreach to vulnerable and underserved populations?

Given the critical nature of vaccine safety and the potential for widespread use of multiple vaccines to defeat the COVID-19 pandemic, every agency involved must coordinate to track and surveil short and long-term effects. This coordination and subsequent transparency in surveillance of vaccine safety is critical to build confidence and trust with the American people. We look forward to your prompt response.

Sincerely,



Bill Pascrell, Jr.
Member of Congress



Robert Menendez
United State Senator